

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

KNOBBE, MARTENS, OLSON & BEAR, LLP
Attn. Delaney, Karoline A.
2040 Main Street
Fourteenth Floor
Irvine, CA 92614
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference

VNUS.069VPC

Date of mailing
(day/month/year)

28/03/2007

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US2006/028454

International filing date
(day/month/year)

21/07/2006

Applicant

VNUS MEDICAL TECHNOLOGIES, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer

Louis Kainde

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference VNUS . 069VPC	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2006/028454	International filing date (day/month/year) 21/07/2006	(Earliest) Priority Date (day/month/year) 21/07/2005
Applicant VNUS MEDICAL TECHNOLOGIES, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 16e
☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/028454

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B18/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/034783 A (MICROSULIS LTD [GB]; CRONIN NIGEL [GB]; GUY ADAM [GB]) 21 April 2005 (2005-04-21)	1-3,5-7, 9,10,13, 14,31, 32,34, 35,37, 39-41
Y	page 11, paragraph 1 - page 15, paragraph 4; figure 8	15,16, 33,38
X	WO 99/11185 A (HOFFMANN STEFFEN [DE]) 11 March 1999 (1999-03-11) claims 11,12; figure 1	1-6,13, 14,18, 23,25-27
X	EP 1 527 748 A (ANGIODYNAMICS INC [US]) 4 May 2005 (2005-05-04) paragraphs [0041], [0043], [0044]; figure 1	42,45
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Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

21 March 2007

Date of mailing of the international search report

28/03/2007

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

MAYER-MARTENSON, E

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/028454

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/199151 A1 (NEUBERGER WOLFGANG [MY]) 7 October 2004 (2004-10-07) paragraphs [0043] - [0045]; figures 1,2	1,5-7,9, 13,14,31
Y	US 6 322 559 B1 (DAULTON JAY S [US] ET AL) 27 November 2001 (2001-11-27) column 10, line 24 - line 47	15,16, 33,38
X,P	WO 2006/069313 A (VNUS MED TECH INC [US]; ZIKORUS ARTHUR W [US]; MCRAE ROBERT GORDON [US] 29 June 2006 (2006-06-29) paragraphs [0037], [0139] - [0153]; figure 15	1-10, 13-16, 31-39, 41-45
X	WO 93/08755 A (EP TECHNOLOGIES [US]) 13 May 1993 (1993-05-13) page 6, line 1 - line 14 page 12, line 21 - line 35 page 21, line 9 - line 33	72-93, 118-131
X	US 5 584 830 A1 (LADD KEVIN C [US] ET AL) 17 December 1996 (1996-12-17) column 8, line 26 - line 62	72-93, 118-145
X	US 6 304 776 B1 (MUNTERMANN AXEL [DE]) 16 October 2001 (2001-10-16) column 6, line 1 - line 28 column 7, line 3 - line 50	72,73, 90,91,93
X	US 2004/059397 A1 (SINOFSKY EDWARD L [US] ET AL) 25 March 2004 (2004-03-25) paragraphs [0026], [0084]	72
X	US 6 183 468 B1 (SWANSON DAVID K [US] ET AL) 6 February 2001 (2001-02-06) column 3, line 28 - column 4, line 12 column 18, line 10 - line 21; figure 13	72-93, 132-136, 138-151, 153
A	US 2004/122420 A1 (AMOA FRANCIS [GB]) 24 June 2004 (2004-06-24) paragraphs [0039], [0040]; figure 5	132,146
X	US 5 441 516 A1 (WANG LIXIAO [US] ET AL) 15 August 1995 (1995-08-15)	155,156, 166-175, 180-184, 187-189
Y	column 6, line 3 - line 10 column 8, line 21 - line 44; figure 6	160,162, 185,186
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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/028454

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 723 094 B1 (DESINGER KAI [DE]) 20 April 2004 (2004-04-20)	155-159, 161, 174-176
Y	column 12, line 36 - line 60; figure 6	160, 185
Y	US 5 588 432 A1 (CROWLEY ROBERT J [US]) 31 December 1996 (1996-12-31) column 23, line 12 - line 39	162, 186
X	WO 98/55046 A (ADIANA INC [US]; HARRINGTON DOUGLAS C [US]; BOWMAN BRETT S [US]; BREIN) 10 December 1998 (1998-12-10) page 6, line 20 - page 7, line 6	155, 156, 163, 165, 174, 177, 179
X	US 5 843 152 A1 (TU HOSHENG [US] ET AL) 1 December 1998 (1998-12-01) column 6, line 30 - line 40	155, 156, 163, 165, 174, 175, 177, 179

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/028454

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 46-71, 94-117
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-45

catheter with energy application device and plurality of
index markers

2. claims: 72-93,118-145

apparatus comprising an energy application device and a
warning device

3. claims: 132-154

system comprising an energy application device and a power
source with performance assessment

4. claims: 155-189

apparatus with therapeutic energy application device and
visibility enhancing element

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/028454

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2005034783	A	21-04-2005	AU 2004279676 A1 CA 2541025 A1 EP 1675519 A1	21-04-2005 21-04-2005 05-07-2006
WO 9911185	A	11-03-1999	DE 19737965 C1 EP 1009305 A1	12-05-1999 21-06-2000
EP 1527748	A	04-05-2005	CA 2482467 A1 US 2005096642 A1	30-04-2005 05-05-2005
US 2004199151	A1	07-10-2004	CN 1832709 A EP 1613393 A2 JP 2006521890 T KR 20060030016 A US 2006217692 A1 WO 2004089462 A2	13-09-2006 11-01-2006 28-09-2006 07-04-2006 28-09-2006 21-10-2004
US 6322559	B1	27-11-2001	AU 4854499 A WO 0001313 A1	24-01-2000 13-01-2000
WO 2006069313	A	29-06-2006	US 2006142824 A1	29-06-2006
WO 9308755	A	13-05-1993	AT 241938 T AU 3067292 A CA 2106410 A1 DE 69233091 D1 DE 69233091 T2 EP 0566725 A1 ES 2201051 T3 JP 3530528 B2 JP 8503381 T US 5383874 A	15-06-2003 07-06-1993 09-05-1993 10-07-2003 06-05-2004 27-10-1993 16-03-2004 24-05-2004 16-04-1996 24-01-1995
US 5584830	A1		NONE	
US 6304776	B1	16-10-2001	AT 307536 T AU 740503 B2 AU 8008898 A CA 2285342 A1 WO 9843547 A2 DE 59813142 D1 DK 0971636 T3 EP 0971636 A2 ES 2249832 T3 JP 2001522265 T	15-11-2005 08-11-2001 22-10-1998 08-10-1998 08-10-1998 01-12-2005 20-03-2006 19-01-2000 01-04-2006 13-11-2001
US 2004059397	A1	25-03-2004	NONE	
US 6183468	B1	06-02-2001	US 6494880 B1	17-12-2002
US 2004122420	A1	24-06-2004	NONE	
US 5441516	A1		NONE	
US 6723094	B1	20-04-2004	AT 294540 T AU 2284100 A WO 0036985 A2 EP 1139897 A2	15-05-2005 12-07-2000 29-06-2000 10-10-2001

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/028454

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6723094	B1	ES 2243090 T3 JP 2002532186 T	16-11-2005 02-10-2002
US 5588432	A1	NONE	
WO 9855046	A 10-12-1998	AT 291889 T AU 758284 B2 AU 7148198 A CA 2311375 A1 DE 69829569 D1 DE 69829569 T2 EP 1005296 A1 ES 2238759 T3 HK 1025240 A1	15-04-2005 20-03-2003 21-12-1998 10-12-1998 04-05-2005 23-03-2006 07-06-2000 01-09-2005 10-06-2005
US 5843152	A1	NONE	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2006/028454

International filing date (day/month/year)
21.07.2006

Priority date (day/month/year)
21.07.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61B18/08

Applicant
VNUS MEDICAL TECHNOLOGIES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

MAYER-MARTENSON, E

Telephone No. +31 70 340-4401



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/028454

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/028454

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 18-41, 46-71, 94-117

because:

☒ the said international application, or the said claims Nos. 46-71, 94-117 relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 18-41 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 46-71, 94-117

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
 - ☒ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
 - ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
 - ☒ all parts.
 - ☐ the parts relating to claims Nos.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/028454

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>4,</u> <u>8,11,</u> <u>12,15-30,</u> <u>33,36,</u> <u>38,40,</u> <u>43,44,74-</u> <u>79,81-</u> <u>88,92,118-131,137,152,154,160,162,164,178,185,186</u>
	No: Claims	<u>1-</u> <u>3,5-7,</u> <u>9,10,</u> <u>13,</u> <u>14,31,</u> <u>32,34,35,</u> <u>37,39,41,</u> <u>42,45,</u> <u>72,73,</u> <u>80,89-91,</u> <u>93,132-</u> <u>136,</u> <u>138-151,153,155-159,161,163,165-177,179-184,187-189</u>
Inventive step (IS)	Yes: Claims	<u>137,152,154,164,178</u>
	No: Claims	<u>1-</u> <u>45,72-</u> <u>93,118-</u> <u>131,132-136,138-151,153,155-163,165-177,179-189</u>
Industrial applicability (IA)	Yes: Claims	<u>1-45,72-93,118-189</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Re Item III.

III.1 METHOD CLAIMS 46-71, 94-117

Method claims 46-71,94-117 define methods for treatment of the human or animal body by therapy or surgery practised on the human or animal body. Therefore no search has been performed for the subject matter of these claims (see Article 17 (2) PCT and Rule 39.1.(iv) PCT) and consequently no written opinion of the International Searching Authority (Rule 43bis.1 PCT) is required for the subject-matter of these method claims.

III.2 INDEPENDENT CLAIMS

Regarding the subject matter of the first invention , the various definitions of the subject-matter given in the plurality of independent claims relating to the first invention, each reciting a different combination of limitations expressed at different levels of generalizations and largely repetitive, are such that the claims as a whole are not clear and concise. The requirements of Article 6 PCT, therefore, are not met.

Consequently, the different combinations of features recited in the plurality of independent claims do not allow to correctly identify "the claimed invention" on which an opinion in the sense of Article 33.1 PCT should be based.

Therefore, this presentation of a number of independent claims makes it difficult, if at all possible, to determine the matter for which protection is sought and places an undue burden to others seeking to establish the extent of monopoly requested.

For this reason a full substantive preliminary examination cannot be carried out until the claims meet Article 6 PCT.

In the following, for the first invention only the independent claims 1,14 and 42 and their dependent claims are examined.

Re Item IV.

The separate groups of inventions are:

claims 1-45:

catheter with energy application device and plurality of index markers

claims 72-93,118-145:

apparatus comprising an energy application device and a warning device

claims 132-154:

system comprising an energy application device and a power source with performance

assessment

claims 155-189:

apparatus with therapeutic energy application device and visibility enhancing element

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

US6322559 discloses a catheter with an energy application device.

Claim 1 further describes a plurality of index markers therefore defining a special technical feature of the first invention.

Independent claims 14,18,27,31,34 and 42 have been grouped in this group of inventions.

Claim 72 further describes a warning device therefore defining a special technical feature of the second invention.

Independent claim 118 has been grouped in this group of inventions.

Claim 132 further describes a source with performance assessment therefore defining a special technical feature of the third invention.

Independent claim 146 has been grouped in this group of inventions.

Claim 155 further describes a visibility enhancing element therefore defining a special technical feature for the fourth invention.

Independent claims 155,174 and 183 have been grouped in this group of inventions.

The special technical features defined for each invention are neither the same nor corresponding since they also solve different problems, namely:

1. determining the position of the energy application device;
2. ensuring patient safety;
3. providing a complete treatment;
4. increasing the visibility of the energy application device;

The application therefore does not fulfill the requirement of unity (Rule 13.1 PCT).

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: WO 2005/034783 A (MICROSULIS LTD [GB]; CRONIN NIGEL [GB]; GUY ADAM [GB])
21 April 2005 (2005-04-21)
- D2: WO 99/11185 A (HOFFMANN STEFFEN [DE]) 11 March 1999 (1999-03-11)
- D3: EP-A-1 527 748 (ANGIODYNAMICS INC [US]) 4 May 2005 (2005-05-04)

- D4: WO 93/08755 A (EP TECHNOLOGIES [US]) 13 May 1993 (1993-05-13)
- D5: US-B1-6 304 776 (MUNTERMANN AXEL [DE]) 16 October 2001 (2001-10-16)
- D6: US 2004/059397 A (SINOFSKY EDWARD L [US] ET AL) 25 March 2004 (2004-03-25)
- D7: US-A-5 584 830 (LADD KEVIN C [US] ET AL) 17 December 1996 (1996-12-17)
- D8: US-B1-6 183 468 (SWANSON DAVID K [US] ET AL) 6 February 2001 (2001-02-06)
- D9: US-A-5 441 516 (WANG LIXIAO [US] ET AL) 15 August 1995 (1995-08-15)
- D10: US-B1-6 723 094 (DESIGNER KAI [DE]) 20 April 2004 (2004-04-20)
- D11: US-A-5 588 432 (CROWLEY ROBERT J [US]) 31 December 1996 (1996-12-31)
- D12: WO 98/55046 A (ADIANA INC [US]; HARRINGTON DOUGLAS C [US]; BOWMAN
BRETT S [US]; BREIN) 10 December 1998 (1998-12-10)
- D13: US-A-5 843 152 (TU HOSHENG [US] ET AL) 1 December 1998 (1998-12-01)

V.1 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (the references in parentheses applying to this document):

*A catheter for use in treating a hollow anatomical structure, the catheter comprising:
an elongated shaft (214) having a distal end and a proximal end;
an energy application device (210) located proximate the distal end of the shaft, the energy
application device having a first length (k); and
a plurality of index markers (704) located along the shaft and proximal of the energy
application device such that consecutive index markers are spaced apart by a second length
(1 cm), the second length comprising an indexing distance of the energy application device
(cf. p.11, par.1 - p.15, par. 4, fig.2a, 8);*

V.2 INDEPENDENT CLAIM 14

The catheter of documents D1 and D2 certainly is sterilized before introducing it into the patient's vein, therefore the method of claim 14 is also disclosed by these documents.

V.3 INDEPENDENT CLAIM 42

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 42 is not new in the sense of Article 33(2) PCT.

The document D3 discloses (the references in parentheses applying to this document):

*An introducer sheath (1,3), comprising:
a sheath lumen (4) having a distal end which is insertable into a hollow anatomical structure, said sheath lumen extending generally along a luminal axis in a distal-to-proximal direction;
an adjustable reference marker (21) connected to said sheath, the longitudinal position, as measured along said luminal axis, of said reference marker being adjustable (par.[0044], fig.1);*

V.4 INDEPENDENT CLAIM 72

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 72 is not new in the sense of Article 33(2) PCT.

Document D4 discloses:

*An apparatus for use in treating a hollow anatomical structure, the apparatus comprising:
an energy application device (16) adapted to receive power from a power source;
a measuring device (76,84) that measures an operating parameter (impedance, temperature) of said energy application device, said operating parameter being relevant to energy coupling between said energy application device and its surroundings;
a module (78) in communication with said measuring device, said module configured to determine whether said operating parameter satisfies a first energy coupling condition within a first time interval following the initiation of power delivery to said energy application device;
and
a warning device (p.12, l.33-35, p.22, l.7-10) in communication with said module, said module further configured to cause the warning device to provide a warning if said operating parameter does not satisfy said first energy coupling condition within said first time interval (cf. p.12 l.21-35; p.21, l.20 - p.22, l.10);*

Also 5 and D6 and D8 disclose all features of present claim 72.

V.5 INDEPENDENT CLAIM 118

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 118 is not new in the sense of Article 33(2) PCT.

Document D7 discloses:

*An apparatus for use in treating a hollow anatomical structure, the apparatus comprising:
a heat application device (12) adapted to receive power from a power source (18);
a user interface (40) adapted to receive a request from a user to initiate power delivery to said heat application device;
a temperature measuring device (30) for measuring a temperature within or near said heat application device;
a module (60) in communication with said temperature measuring device and said user interface, said module configured to determine whether a temperature measured by said temperature measuring device satisfies a required initial temperature condition; and
said module further configured to follow a safety procedure to interrupt a normal power-up process for the heat application device if said temperature measured by said temperature measuring device does not satisfy said required initial temperature condition (cf. col.8, l.26-62).*

V.6 INDEPENDENT CLAIM 132

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 132 is not new in the sense of Article 33(2) PCT.

Document D7 discloses:

A hollow anatomical structure therapy system comprising:
an energy application device (108) suitable for insertion into a hollow anatomical structure;
a power source (106) in communication with said energy application device, said power source comprising a processor (102) and program instructions executable by said processor such that said power source is operable to:
(a) deliver power to said energy application device during a first power delivery phase;
(b) measure time elapsing during power delivery;
(c) assess performance of said therapy system during said first power delivery phase; and
(d) if said performance of said therapy system during said first power delivery phase is satisfactory, deliver power to said energy application device during a second power delivery phase (cf. par.18, l.10-21);

V.7 INDEPENDENT CLAIM 146

For similar reasons as given in § V.6 also the subject matter of claim 146 lacks novelty in the

sense of Article 33(1) and (2) PCT.

V.8 INDEPENDENT CLAIM 155

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 155 is not new in the sense of Article 33(2) PCT.

Document D9 discloses:

*An apparatus for treating a hollow anatomical structure, said apparatus comprising:
an elongate shaft (18);
a therapeutic energy application device (50) coupled to said shaft, said energy application device being sized for insertion into a hollow anatomical structure; and
at least one visibility-enhancing element (64,66) near said energy application device (cf. col.6, l.3-10, col.8, l.21-44; fig.6).*

Also documents 10-13 disclose all features of claim 155.

V.9 INDEPENDENT CLAIMS 174,183

For similar reasons as given in § V.8 also the subject matter of claims 174 and 183 lacks novelty in the sense of Article 33(1) and (2) PCT.

V.10 DEPENDENT CLAIMS

Dependent claims 2-17,73-93,119-131, 133-136,138-145,147-151,153, 156-163,165-173,175-177,179-183,185-189 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see the document and the corresponding passages cited in the search report.